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Health Science Funding, LLC Plaintiff vs. The United States Food & Drug Administration and Margaret A. Hamburg, in her official capacity as Commissioner of The FDA Defendants	UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY Civil Action # **VERIFIED COMPLAINT**

Plaintiff Health Science funding LLC, by its undersigned attorneys, as and for its Complaint in this matter, avers and alleges as follows:

NATURE OF THE ACTION

1. Plaintiff markets Prastera® brand DHEA, a Medical Food for women with lupus. On Sept. 13, 2012 Plaintiff asked defendant The U.S. Food & Drug Administration (FDA) to review the Prastera® label and confirm that it complies with 21 U.S.C. § 360ee(b)(3).

2. FDA responded that it has "serious questions" with that labeling. The two questions FDA raised, however, are as a matter of law simply not relevant to 21 U.S.C. § 360ee(b)(3). FDA's two questions thus fail to provide any basis to dispute that Plaintiff's label complies with 21 U.S.C. § 360ee(b)(3).

3. FDA appears fully aware of the legal irrelevance of its questions, for two reasons. First, while FDA says its questions are "serious," FDA flatly refuses to memorialize them. Second, while FDA verbally threatens Plaintiff with enforcement action, FDA has for nearly a year pointedly avoided taking any.

4. While FDA appears aware that its alleged questions are not legally relevant, its explicit threat of enforcement action leaves Plaintiff exposed to the risk of arbitrary and capricious agency enforcement action. Plaintiff accordingly ask this Court to issue a *Declaratory Judgment* that its label complies with 21 U.S.C. § 360ee(b)(3). In the interim, Plaintiff respectfully asks this Court to issue a *Preliminary Injunction* maintaining the *status quo*, enjoining FDA from taking any enforcement action against Plaintiff's product.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1346 (jurisdiction where the United States is a defendant).

6. The Plaintiff's requested relief is authorized under Fed. R. Civ. P. 65(a) (preliminary injunction), 28 U.S.C. § 2201 (declaratory relief) and 28 U.S.C. § 2202 (further relief).

7. Venue is properly vested in this Court under 28 U.S.C. § 1391(e)(3) because the Plaintiff resides in this District and no real property is involved in this action.

THE PARTIES

8. **Plaintiff**: Health Science Funding, LLC is a New Jersey limited liability company with its principle place of business in Morristown, NJ.

9. **Defendants**: The United States Food and Drug Administration (FDA) is part of the United States Department of Health and Human Services (HHS), an executive branch agency. Dr. Margaret A. Hamburg (named in her official capacity only) is the Commissioner of the FDA.

OVERVIEW

10. DHEA is widely sold as a dietary supplement; it is available at e.g., Wal*Mart, General Nutrition Center and amazon.com. *See* M. Pohl, *Declaration* (June 2013) (hereinafter, "Dec.") at Exhibit 1 ("Dec.Ex.1").

11. For many consumers, DHEA dietary supplements are a waste of money. DHEA is secreted by the adrenal cortex, Dec.Ex.2, and excess DHEA is simply excreted in the urine, Dec.Ex.3 at 220 Table IV. Thus, DHEA dietary

supplements, while not harmful, may not provide much benefit to many consumers.

12. DHEA is extremely valuable, however, for a particular group of people: women with systemic lupus erythematosus. Female lupus patients have below-normal levels of DHEA. Dec.Ex.4 at 244 Fig. 1. Taking DHEA restores lupus patients' DHEA level to a normal, healthy level. This simple change has a dramatic effect on health.

13. Lupus is an auto-immune disease. It is somehow hormone-related: ninety percent of patients are women, most of child-bearing age. Dec.Ex.6 at Results, pg. 2250 col. 2 to 2251 col. 1. Lupus destroys the kidneys, causing complete kidney failure. *Id*. at Table 1. Lupus attacks the circulatory system, causing cardiac failure, even in quite young women. *Id*. Lupus interferes with the body's normal immune function, so lupus patients have a frighteningly high risk of death from cancer, and are at grave risk of dying from simple infections and pneumonia. *Id*.

14. Given the lifelong nature of the disease, its crippling effect on one's ability to raise a family, or even hold a steady job, and the chronic pain it causes, it is perhaps not surprising that lupus patients have another significant cause of death:

suicide. Dec.Ex.7. All told, in the U.S. alone, lupus kills nearly 5 people a day, every day.[1]

15. Taking DHEA, however, minimizes this. For example, DHEA reduces the frequency and severity of the autoimmune "flares" which damage lupus patients' skin and internal organs. E.g., Dec.Ex.9, Ex. 10 at Fig. 1 and Table 2; Ex. 11 at Table 3.

16. DHEA cuts the risk of breast cancer in half. Dec.Ex.12 pg. 98.

17. And perhaps most encouraging for women with lupus (and for their families), it reduces the risk of death from any cause ***by a stunning 80%***: a far greater benefit than many drugs achieve. Dec.Ex.12 pg. 86-87. That means that of the nearly five women lupus kills every day, DHEA could save the lives of almost four.

18. DHEA has for decades been widely available as a dietary supplement. *See* Dec.Ex.1, Ex. 13 pg. 9 § 6 (discussing public use as early as 1995). One could fairly ask why in the world lupus patients do not take DHEA dietary supplements.

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[1] The U.S. Center for Disease Control says there are 52 lupus deaths per year per 10 million population. *See Trends In Deaths From Systemic Lupus Erythematosus - United States, 1979 - 1998*, 51 CDC Weekly 371-4 (May 2, 2002). The U.S. Census Bureau estimates the U.S. population was 315MM in March 2013. See *Monthly Population Estimates for the United States: April 1, 2010 to March 1, 2013* (NA-EST2012-01). This works out to 1,638 lupus deaths per year, or 4.5 deaths per day.

19. First, DHEA dietary supplements have unreliable purity. Dec. Exs. 8 and 14. Indeed, concern over the lack of a minimum quality standard has prompted several physicians to expressly advise patients to avoid DHEA dietary supplements. For example, no less authority than THE JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION "recommends that people not take DHEA on their own":

> [Professor John Renner, M.D.] "recommends that people not take DHEA on their own. Recalling the impurities in tryptophan … led to a number of deaths and hundreds of cases of eosinopilia-myalgia syndrome, Renner notes that there is still no governmental regulation of the potency and purity of so-called nutritional supplements."

Dec.Ex.15 pg. 1367 col. 3.

20. Further, without physician guidance, lupus patients may not understand DHEA's benefit, nor know how much of it to take, nor how often to take it, nor when to stop taking it (e.g., if pregnant), nor what side effects to expect. Further, health insurance plans generally refuse to cover dietary supplements.

21. To address these needs, Plaintiff developed a pharmaceutically-pure DHEA product for sale not as a dietary supplement, but as a "Medical Food," *i.e.*, a food product which, while merely a food, is nonetheless available only for use under physician supervision, to address a specific medical condition (rather than general health / well-being). *See* 21 U.S.C. § 360ee(b)(3). Plaintiff's product is thus, at core, merely a safer version of currently-available dietary supplements, a version intended for use under physician supervision.

22. Plaintiff designed its product to conform to the statutory definition of Medical Food. The term "Medical Food" is defined by statute:

> "The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

See 21 U.S.C. § 360ee(b)(3).

23. A "Medical Food" must thus meet several statutory elements. It must be consumed orally (enterally). It must be used under physician supervision. It must be intended for a particular disease or condition, not simply for general health and well-being. And, the physician must make a medical evaluation to confirm that the patient in fact has distinctive nutritional requirements for that food.[2]

24. To address these needs, Plaintiff developed a pharmaceutically-pure DHEA product. Dec.Ex. 16 and 17.

25. Plaintiff designed its product labeling to fulfill each element of the statutory definition of Medical Food. The product is formulated to be consumed orally.

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[2] Products which qualify as Medical Food are exempt from health claim labeling requirements, *see* 21 U.S.C. § 343(r)(1), (r)(5)(A); 21 C.F.R. § 101.14(f)(2), and are exempt from "Nutrient content" (e.g., serving size, calorie count) labeling, *see* 21 USC § 343(q)(1). While "medical," however, a Medical Food remains a food, and thus must comply with food-purity standards. Also, the label must contain a statement of identity (the common name of the product) (21 CFR 101.3), the net quantity of contents (21 CFR 101.105), the name and place of business of the manufacturer (21 CFR 101.5), and a complete list of ingredients (21 CFR 101.4).

Dec.Ex.17 at § 2.1. The product is intended for use under the supervision of a physician. Dec.Ex.17 at § 1. The product is intended to manage a specific condition: the product is for female patients with active systemic lupus erythematosus. Dec.Ex.17 at § 1.

26. Lupus patients have a distinctive nutritional requirement for DHEA. Lupus patients have depressed levels of DHEA. *See* Dec.Ex.4 at 244 Fig. 1. Consuming DHEA restores lupus patients' DHEA levels to normal. Restoring DHEA levels to normal decreases the risk of auto-immune flare, Dec.Ex.10 and 11, decreases risk of breast cancer, Dec.Ex.12 at pg. 98, and reduces risk of death from any cause, Dec.Ex.12 at pg. 86-87.

27. The physician must make a medical evaluation to establish that the patient in fact has a distinctive nutritional requirement for DHEA. *See* Dec.Ex.17 at § 1.

28. Thus, while the active ingredient in Plaintiff's product is already widely available as a dietary supplement, Plaintiff's product incorporates physician monitoring and pharmaceutical-grade purity, safeguards which make it, if anything, safer than existing dietary supplements.

29. On Sept. 13, 2012, Plaintiff asked FDA to vet Plaintiff's product label. Dec.Ex.18. The statute requires the physician's medical evaluation be "based on recognized scientific principles." Plaintiff accordingly included with its submission certain published clinical studies showing DHEA's effectiveness, and

thus showing how physicians' medical evaluations are rationally "based on recognized scientific principles."

30. FDA responded that it had "serious questions and concerns" with the labeling. Dec.Ex.19. FDA did not, however, disclose what those "questions and concerns" were. *Id.*

31. Plaintiff thus asked FDA to identify its "questions and concerns." Dec.Ex. 20, 21.

32. FDA responded via voice mail. Dec.Ex.22. FDA acknowledged that the scientific literature shows DHEA helps lupus patients. *See* Dec.Ex.22. FDA, however, noted that "efficacy alone does not qualify a product to be marketed as a medical food." *Id.* FDA said it has two "questions and concerns" on Plaintiff's labeling.

33. First, FDA noted that products freely available to consumers (e.g., DHEA dietary supplements) are not "automatically" Medical Foods under the statute. Dec.Ex.22; Dec.Ex.23 at M. Pohl, email (Jan. 24, 2013). While this statement may be correct, however, it is not relevant. The question at hand is not whether all dietary supplements in the abstract "automatically" meet the statutory definition of Medical Food, but whether Plaintiff's particular labeling in fact does so.

34. Second, FDA advised that it is "not aware of any distinctive nutritional requirements" for lupus. Dec.Ex.22.; Dec.Ex.23 at M. Pohl, email (Jan. 24, 2013).

FDA's ignorance of lupus patients' requirement for DHEA, however, is not relevant as a matter of law. This is because the statute requires that the "distinctive nutritional requirement" be established not by FDA, but by "medical evaluation" - *i.e.*, by the patient's physician. The statute says:

> "The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

See 21 U.S.C. § 360ee(b)(3) (underlining mine). FDA ignorance of physicians' medical evaluations is entirely understandable, because patient medical records are confidential and because FDA does not (and cannot) require patients to submit them to FDA for review. FDA ignorance of those medical evaluations, however, is not legally relevant under the statute. *Id.*

35. To resolve FDA's two concerns, Plaintiff attended an in-person meeting with FDA. *See* Dec.Ex.23. At that meeting, FDA reiterated its two concerns: dietary supplements are not "automatically" Medical Foods, and FDA is not aware of any "distinct nutritional requirement" for DHEA in lupus patients.

36. Further, FDA threatened enforcement action. FDA noted (correctly) that it can seize mislabeled product, FDA alleged that it had in fact recently seized another manufacturer's mislabeled product, and FDA threatened to seize Plaintiff's product as allegedly not complying with 21 U.S.C. § 360ee(b)(3). FDA also

demanded "immediate remedial action," but failed to say what remedial action would possibly be needed.

37. FDA's seizure threat is credible in light of FDA's numerous similar threats against other medical food manufacturers. Dec.Ex.24. Troublingly, FDA's various Warning Letters to other manufacturers occasionally present legal positions contrary to the Medical Food statute, and indeed contrary to FDA's own regulations.

38. Further, FDA's various Warning Letters appear specifically designed to frustrate judicial review: they uniformly threaten product seizure *within 15 days*, Dec.Ex.24, denying a reviewing Court much time to review a dispute.

39. Given FDA's threat of product seizure, a threat credible in light of FDA's pattern of enforcement against other manufacturers, *see* Dec.Ex.24, Plaintiff respectfully asks this Court for a Declaratory Judgment confirming that Plaintiff's product label conforms to the statutory definition of Medical Food articulated in 21 U.S.C. § 360ee(b)(3).

40. In the interim, Plaintiff respectfully ask the Court for a Preliminary Injunction maintaining the status quo and barring FDA from commencing any enforcement action against Plaintiff's product.

COUNT I - THE COURT SHOULD ISSUE A DECLARATORY JUDGMENT THAT PLAINTIFF'S PRODUCT COMPLIES WITH THE STATUTORY DEFINITION OF MEDICAL FOOD

41. This Court should issue a declaratory judgment under 28 USC § 2201(a) that Plaintiff's labeling meets the statutory definition of Medical Food in 21 U.S.C. § 360ee(b)(3).

42. Declaratory judgment avails to resolve questions of law on relatively undisputed facts. *See* Fed. R. Civ. P. Rule 57 at Advisory Comm. notes. For example, the Court may use a Declaratory Judgment to construe a statute. *Id*.

43. The instant case involves a straightforward issue of statutory construction. The Federal Food Drug & Cosmetic Act defines "Medical Food":

> "The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

See 21 U.S.C. § 360ee(b)(3). Thus, any food which is used under physician supervision, formulated to be consumed orally, is intended for a particular disease or condition, and which requires the physician to make a medical evaluation to confirm that the patient in fact has distinctive nutritional requirements is, as a matter of law, a Medical Food under the statute.

44. In the instant case, Plaintiff's product labeling confirms that the product meets each and every one of the statute's elements. *See* Dec.Ex.17, *supra* ¶¶ 25-

27. Plaintiff's product label thus meets the statutory definition of Medical Food. *See* 21 U.S.C. § 360ee(b)(3).

45. Plaintiff respectfully asks the Court to issue a Declaratory Judgment pursuant to 28 U.S.C. § 2201, confirming that Plaintiff's product meets the statutory definition of Medical Food.

46. FDA argues that it knows of no "distinctive nutritional requirement" for DHEA in lupus patients. Dec.Ex.22; Dec.Ex.23 at M. Pohl, email (Jan. 24, 2013). FDA's alleged ignorance, however, is legally immaterial because the statute says that requirement must be established by physicians, not by FDA. *See* 21 U.S.C. § 360ee(b)(3). The statute articulates procedure for physicians to do so (a medical evaluation) and a standard for that procedure (based on scientific principles). *Id.* Indeed, the statute does not even mention the FDA. *Id.* Thus, the plain language of the statute gives physicians, not the FDA, authority to make this evaluation.

47. The FDA apparently recognizes that it lacks authority to make this evaluation. It has steadfastly refused to put in writing its ostensible legal position. *See* Dec.Ex. 19, Dec.Ex.22; Dec.Ex.23 at M. Pohl, email (Jan. 24, 2013). And, while it threatens Plaintiff with enforcement action, FDA has circumspectly avoided in fact taking any.

COUNT II - PENDING ISSUANCE OF ITS DECLARATORY JUDGMENT, THE COURT SHOULD PRESERVE THE *STATUS QUO* AND ENJOIN FDA FROM TAKING ENFORCEMENT

ACTION AGAINST PLAINTIFF'S PRODUCT

48. Until this Court rules on whether Plaintiff's product meets the statutory definition of Medical Food, the Court should enjoin FDA from taking any enforcement action against Plaintiff.

49. Preliminary injunctions are intended to maintain the *status quo* pending a final adjudication. *See Opticians Ass'n of Am. v. Indep. Opticians of Am.*, 920 F.2d 187, 197 (3d Cir. 1990). In the instant case, Plaintiff submitted its product labeling to FDA in September, 2012. Dec.Ex.18. Since then, FDA has threatened product seizure, but has not in fact attempted to seize Plaintiff's product, nor issued a Warning Letter to Plaintiff, nor taken any other enforcement action against Plaintiff nor its product. To the contrary, FDA has refused to even memorialize its alleged "serious questions and concerns." *See* Dec.Ex. 19, Dec.Ex.22; Dec.Ex.23 at M. Pohl, email (Jan. 24, 2013). Thus, today Plaintiff remains free to market its product.

50. To preserve this *status quo*, this Court should enjoin FDA from taking enforcement action until this Court has issued a Declaratory Judgment. *See Opticians Ass'n of Am.*

51. To issue a preliminary injunction, a court must consider four factors: 1) Whether the moving party demonstrates a "reasonable probability" of success on the merits, 2) Whether the moving party may be irreparably injured in preliminary relief is denied, 3) Whether granting preliminary relief will result in even greater

harm to the non-moving party, and 4) Whether preliminary relief will be in the public interest. *See e.g., Novartis Consumer Health v. Johnson & Johnson - Merck Consumer Pharmaceuticals Co*., 290 F.3d 580, 586 (3rd Cir. 2002). In this case, all four factors support granting an injunction.

Plaintiff Demonstrates A "Reasonable Probability" Of Success On The Merits

52. Plaintiff demonstrates a reasonable probability of success on the merits. Plaintiff's labeling meets each and every element required by the statute. Dec.Ex.17; *supra at* ¶¶ 25-27.

53. Indeed, FDA tacitly concedes this. FDA has threatened Plaintiff verbally with enforcement, but has for nearly a year refrained from instituting any enforcement action, and flatly refuses to explain in writing its alleged concerns with Plaintiff's labeling. FDA's nearly year-long refusal to act shows that FDA itself believes Plaintiff will win on the merits.

Plaintiff Will Be Irreparably Injured If Preliminary Relief Is Denied

54. Plaintiff will be irreparably harmed if preliminary relief is denied.

55. The Court of Appeals for the Third Circuit instructs that for a preliminary injunction analysis, "irreparable harm" includes potential loss of future sales and market share. *See Novartis Consumer Health v. Johnson & Johnson - Merck Consumer Pharmaceuticals Co*., 290 F.3d 580, 596 (3rd Cir. 2002). In the instant

case, FDA's threat of seizure chills Plaintiff's willingness to distribute its product, and chills physicians' willingness to prescribe it. This potential loss of future sales and market share is "irreparable harm." *See Novartis Consumer Health* at 596.

56. FDA may argue that Plaintiff's alleged future loss is merely speculative. Speculative injury, however, suffices for relief. The Third Circuit instructs that a manufacturer must merely establish that it has a "reasonable basis" for believing that it is "likely to suffer injury." *Id*. at 595. A manufacturer "need not come forward with specific evidence that the challenged claims actually resulted in some definite loss of sales." *Id*. In the instant case, FDA's threat of enforcement action provides a reasonable basis to believe Plaintiff will suffer lower sales and market share.

Preliminary relief will not harm the FDA

57. Preliminary relief will not harm the FDA. Indeed, FDA tacitly concedes this. While verbally threatening Plaintiff with enforcement action, FDA has pointedly refrained from taking enforcement action for nearly a year. FDA's long period of inaction shows that FDA recognizes that neither FDA nor the public has been harmed by, nor will not be harmed by, the status quo.

58. One of the goals of preliminary injunctions being "to maintain the *status quo*," *see Opticians Ass'n of Am. v. Indep. Opticians of Am*., 920 F.2d 187, 197 (3d

Cir. 1990). Here, preliminary relief merely preserves the *status quo* created by the FDA's own inaction.

Preliminary relief advances a critical public interest.

59. The most cogent reason to preserve the status quo, however, involves neither Plaintiff nor FDA, but lupus patients.

60. As mentioned above, every day, lupus kills almost 5 people in the U.S. *See supra* ¶¶ 13-14. Most victims are women, many are young. *Id*. And lupus is not an easy death: kidney failure, cancer, routine infection and suicide. *Id*.

61. The active ingredient in Plaintiff's product does not cure lupus, but helps. It reduces the risk of auto-immune flares, Dec.Ex.10 at Fig. 1 and Table 2 and Dec.Ex.11 at Table 3, it reduces the risk of hormone related breast cancer, Dec.Ex.12 at pg. 98, and it reduces the risk of death from any cause ***by a stunning 80%***, Dec.Ex.12 at pg. 86-87. Thus, of the nearly five women lupus kills every day, Plaintiff's product could save the lives of 3 or 4. *See id*.

62. Further, DHEA is known to be safe. It has been commonly available in the U.S. for decades, and is already widely sold as a dietary supplement. Dec.Ex.1. FDA's own internal reviews indicate that it is safe. Dec. Exs. 13 and 25.

63. Allowing Plaintiff to continue to market it product advances the public interest because it enables vulnerable patients to better access a safe, potentially

life-saving product, and enables physicians to better care for these vulnerable patients without fear of arbitrary FDA enforcement action.

Saving The Lives Of Four Women A Day Is
Not A Bad Day's Work For Your Honor

64. This case thus gives Your Honor a somewhat rare opportunity: how often can you go home in the evening and tell your family that you saved four innocent women's lives today? How often can you say that you helped save four women's lives today, and another four tomorrow, and another four every tomorrow for years into the future? This case gives this Court the opportunity to create quite a legacy.

The Court Must give Defendants at least Five Days
Notice Of A Preliminary Injunction Hearing

65. To grant a preliminary injunction, the Court must give Defendants at least five days advance notice of the preliminary injunction hearing. *See* Hon. M. Denlow, *The Motion for a Preliminary Injunction*, 22 REV. LIT. 495, 505-06 (2003), *citing* Fed. R. Civ. P. Rule 6(d).

66. The Court may consolidate the preliminary injunction hearing with the trial on the merits. *See* Fed. R. Civ. P. 65(a)(2). To consolidate, the Court must provide adequate notice to the parties. *See Anderson v. Davila*, 125 F.3d 148, 157 (3rd Cir. 1997). Plaintiff respectfully suggests that the instant case - with undisputed facts and a simple statute - appears amenable to such an expedited resolution.

67. In granting a preliminary injunction, the Court must enter findings of fact and conclusions of law. *See* Fed. R. Civ. P. Rule 52(a). Plaintiff respectfully believes the enclosed proposed Order does this.

PRAYER FOR RELIEF

68. FDA alleges it has "serious questions and concerns," yet flatly refuses to reduce those concerns to writing. Plaintiff thus asks this Court to issue a Declaratory Judgment holding that Plaintiff's product label meets the statutory definition of Medical Food in 21 U.S.C. § 360ee(b)(3).

69. FDA verbally threatens Plaintiff with enforcement action, yet has scrupulously refrained from in fact taking any. To preserve the *status quo* created by FDA's own decision to refrain from enforcement action, Plaintiff asks this Court to enjoin FDA from taking enforcement action against Plaintiff. Plaintiff accordingly respectfully asks this Court to:

A. **Issue an Order to Show Cause** under Local Civil Rule 65.1 requiring FDA to show cause why a preliminary injunction should not issue enjoining FDA from taking enforcement action against Plaintiff and its product; and
B. **Temporarily Enjoin** FDA from commencing enforcement action against Plaintiff and its product until the Court issues a Declaratory Judgment; and
C. **Declare** in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act) that Plaintiff's product complies with the statutory definition of "Medical Food" under 21 U.S.C. § 360ee(b)(3); and
D. **Permanently Enjoin** FDA from taking enforcement action against Plaintiff's Product for so long as its labeling complies with the statutory definition of "Medical Food" under 21 U.S.C. § 360ee(b)(3).
E. **Order such other relief** and the Court deems necessary and proper to prevent FDA from taking arbitrary and capricious enforcement action against Plaintiff, its agents or its product.

Respectfully submitted on behalf of Plaintiff
Health Science Funding LLC by its attorneys,
PHARMACEUTICAL PATENT ATTORNEYS LLC

_/s Mark Pohl_____
Mark Pohl, Esq.

VERIFICATION

I, J. Mark Pohl, attorney for Health Science Funding LLC, have read the foregoing Verified Complaint. Based on my personal knowledge, I hereby certify that the statements set forth in this Complaint are true and accurate.

The matter in controversy is not subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

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J. Mark Pohl

Dated as of June 12, 2013.